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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/701,278	08/22/96	ANDERSON D	A-63770-1/RF

HM12/0116
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EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1647	29

DATE MAILED: 01/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/701,278	Applicant(s) Anderson et al
	Examiner Robert C. Hayes	Group Art Unit 1647

☒ Responsive to communication(s) filed on *Oct 20, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 2, and 4-7* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, and 4-7* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/20/00 has been entered.

2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

3. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper No. 26, and as follows.

Applicants argue on page 3 of the response that the disclosed utility on page 20 of the specification is " 'specific' and 'substantial' in view of the Revised Interim Utility Guidelines", and that "this utility [is not] akin to disclosing a 'gene probe' or 'chromosome marker' in the absence of a disclosure of a specific DNA target". In contrast to Applicants' assertions, no "specific utility" exists for the claimed polynucleotides at the time of filing the instant specification, because many genes are expressed in peripheral sensory neurons; thereby, being more "akin to a gene probe or chromosomal marker", and not being specific, by definition (especially as it relates to the genus of hybridization products claimed). And because the "specific" function of the encoded DRG11 gene is further not known, nor described within the instant specification. In other words,

without knowing the specific function of the encoded DRG11 protein, even the preferred nucleic acid embodiment depicted as SEQ ID NO:1 can have no "specific" utility, by definition. Note further that the claims are not limited to the preferred and described DRG11 polynucleotide sequence of SEQ ID NO:1 (i.e., as it relates to claims 1, 2 & 5-7).

Applicants argue on pages 3-4 of the response that "[s]uch markers can be used to obtain or isolate pools of such [peripheral sensory] neurons"; thereby, establishing a "substantial" utility "for investigation of neurodegenerative diseases or neural injury". Applicants then argue that "[t]his utility is not the same as merely allowing for further research to characterize the marker protein, nor is it the same as being directed to treating an unspecified disease". In contrast to Applicants' assertions, because "further research" is required for "investigation of neuro-degenerative diseases or neural injury", by definition, no "substantial" utility can exist, by definition. In other words, further experimentation is still necessary at the time of filing the instant invention to attribute a "real world" utility to the claimed polynucleotides, as previously made of record. Again, the rationale is that one would expect that a limited number of dysfunctional genes would be useful as markers for diseases, versus a generalized "molecular marker to identify neurons in the peripheral sensory lineage" or the generalized "markers... [that may be useful] to obtain or isolate pools of such [peripheral sensory] neurons. Thus, Applicants' arguments are not persuasive, for the reasons made of record.

4. Claims 1-2 & 4-7 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper No. 26.

5. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 26, and as follows.

In contrast to Applicants' assertions on page 4 of the response, the issue remains that one of ordinary skill in the art cannot visualize what nucleic acid sequences are specifically encompassed by the current claims (i.e., by SEQ ID NO; as it especially relates to the 5' or 3' sequences encompassed by the current open claim language, and for the undescribed hybridization products claimed); nor could one visualize what constitutes generic sequences encompassed by these claims based solely on the written description of the single cDNA sequence of SEQ ID NO:1. Additionally, because no known nor disclosed function exists for the encoded DRG11 protein of the instant invention, what constitutes a functional allelic variant (i.e., as it relates to the hybridization products claimed) cannot be reasonably determined at the time of filing Applicants' invention.

Accordingly, *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) held that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Moreover,

"[o]ne skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function [i.e., "wherein the first polynucleotide sequence detects *Staphylococcus aureus*"], as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is". *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

Note further that the recitation "recombinant" nucleic acids does not reasonably distinguish the nucleic acid of SEQ ID NO:1 from any different nucleic acid sequence encompassed by the current claims.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
January 2, 2001

Gary L. Kunz

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